# EC declaration of conformity

CE

*According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device*

**Manufacturer:** Xiamen Wiz Biotech CO., LTD.

**Address:** 3-4 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R.China

EC REP **EU representative:** WellKang Ltd

**Address:** Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

**Product Name:** SARS-CoV-2 Antigen Rapid Test

**Product Type:** 1 Test/kit, 2 Tests/kit, 3Tests/kit, 5 Tests/kit, 10Tests/kit, 20Tests/kit, 25Tests/kit, 30Tests/kit, 40Tests/kit, 50Tests/kit, 100Tests/kit, 200Tests/kit

**Product Classification: Other IVD device**

**We hereby state that:**

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives IVDD98/79/EC, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

**Directive we are following:**

*In-Vitro Diagnostic medical device:*
*DIRECTIVE 98/79/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October1998 on In-Vitro Diagnostic medical device.*

**Standards we are implementing:**

| | | |
|---|---|---|
| *EN 13612:2002/AC: 2002* | *EN ISO 13485:2016* | *EN ISO 14971:2012* |
| *EN ISO 23640:2015* | *EN 13641:2002* | *EN ISO 15223-1:2016* |
| *EN ISO 18113-1:2011* | *EN ISO 18113-2:2011* | |

Xiamen Wiz Biotech CO., LTD.

**XiaMen. China** **August 10, 2020**

***Place*** ***date*** ***Signature, Title***

# SARS-CoV-2 Antigen Rapid Test

## Clinical report summary

• Comparative analysis of test reagent results with PCR test results

The detection results of test reagent and the PCR test results were shown in the following table:

| | | PCR test results | | Total |
|---|---|---|---|---|
| | | Positive (+) | Negative (-) | |
| Test reagent results | Positive (+) | 78 | 0 | 78 |
| | Negative (-) | 3 | 257 | 260 |
| Total number | | 81 | 257 | 338 |

Sensitivity: 96.3%;（95%CI：89.67%~98.73%）

Specificity:100 %;（95%CI：98.53%~100%）

Total clinical coincidence rate: 99.11%.（95%CI：97.42%~99.70%）

The above results showed that there was no statistically significant difference between the detection reagent and the PCR results。

**Xiamen Wiz Biotech Co.,LTD.**
Address:3-4 Floor,NO.16 Building,Bio-medical Workshop,2030 Wengjiao West Road,Haicang District,361026,Xiamen,China
Tel:+86-592-6808278 Fax:+86-592-6808279